

### REMARKS

The Office Action mailed July 16, 2003 has been received and reviewed. Claims 1-36 are pending in the application, while claims 2-5, 7-9, and 11-31 have been withdrawn from consideration. Claims 1, 6, 10, and 32-36 stand rejected. The application is to be amended as previously set forth. Claims 33 and 36 are to be canceled. All amendments and claim cancellations are made without prejudice or disclaimer. It is respectfully submitted that no new matter has been added. Reconsideration is respectfully requested.

#### 1. Examiner Interview:

Applicant would like to thank the Examiner and her supervisor for the courtesy extended applicant and his representative at the interview of August 7, 2003. Applicant found the interview extremely useful in understanding the issues and believes that the interview should expedite the examination process.

#### 2. The Claim Rejections:

Claims 1, 6, 10, and 32 are rejected under 35 U.S.C. § 102(b) as being anticipated by US Patent 5,983,130 to Phipps et al. ("Phipps"). Applicant respectfully traverses the rejection.

As discussed at the interview, Phipps discloses an electrotransport agent delivery apparatus utilizing a pulsating square-wave current discharge to deliver the agent. (*See, e.g.*, FIGs. 2 & 4 of Phipps).

As also discussed at the interview, applicant's invention as claimed in claim 1 is directed to a device that uses a single (*i.e.*, non-pulsating) square-wave current discharge. Applicant has accordingly amended independent claim 1 to clarify that the claimed iontophoretic fluid delivery device comprises "a first electromotive cell constructed to produce a single, approximately square-wave current discharge over the first electromotive cell's working life", *i.e.*, there is no pulsation or oscillation as found in Phipps. Basis for the amendment is inherent throughout the application, but specific basis can be found, among other places, in paragraph [0039] and associated FIG. 5 of the application as filed. As Phipps does not disclose "a first electromotive cell constructed to produce a single, approximately square-wave current discharge over the first

electromotive cell's working life", it cannot anticipate amended claim 1 or claims 6, and 10 dependent thereon.

With respect to claim 1, it has also been amended (claim 32 has been similarly amended) to include the element of claim 33, *i.e.*, a shunt resistance disposed in parallel with an ion conducting path between the cationic and anionic chambers, the shunt resistance selected to control the delivery of fluid from the iontophoretic fluid delivery device. Basis for the amendment is inherent throughout the application, but specific basis can be found, among other places, in original, elected claim 33 and paragraph [0057] of the application as filed.

As discussed at the interview and disclosed in the application (*see, e.g.*, FIG. 11 and paragraph [0057]), a "shunt resistor,  $R_p$ , can be connected in-circuit to form an electron conducting path in parallel to the ion conducting path through a body. \* \* \* As is well known in electric circuit design, the current flow through the shunt resistor  $R_p$  and the body resistance  $R_s$  will be determined by the relative magnitude of the resistance in each path. Decreasing the value for  $R_p$  increases the current flow through the parallel path, and decreases the current flow through the ion conducting path, resulting in a lower dispensed beneficial agent ion dose. A device may therefore be constructed to deliver a dose of ion-based treatment corresponding to any portion of a battery's capacity." In particular, the shunt resistor can be used to adapt downwards an inexpensive, readily commercially available mini battery's capacity so as to be useful in the delivery of a drug through skin.

Such a feature is not disclosed by Phipps and Phipps thus cannot anticipate claims 1 and 32 and the claims dependent from claim 1 for this reason.

With respect to claim 32, it has been amended to identify that the electromotive force is a mini battery together with a shunt resistor. Basis for this amendment is found in elected (now to be canceled) claim 36 and in paragraphs [0040], [0041], [0042], and [0056] of the application as filed. Mini batteries are readily commercially available (*e.g.*, watch or other "button-type" batteries) and inexpensive.

Furthermore, as previously identified, claim 32 has been further amended to include the element of elected claim 33, *i.e.*, a shunt resistance disposed in parallel with an ion conducting path between the cationic and anionic chambers, the shunt resistance selected to control the

delivery of drug from the disposable iontophoretic fluid delivery device dependent on the mini battery. Basis for the amendment is inherent throughout the application, but specific basis can be found, among other places, in original, elected claim 33 and paragraph [0057] of the application as filed.

Phipps does not disclose such a shunt resistance or its utility in being able to adapt inexpensive mini batteries for application in the device of claim 32. Accordingly, claim 32 cannot be anticipated by Phipps.

Claims 32-36 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 6,421,561 to Morris. Applicant respectfully traverses the rejection.

As amended, independent claim 32 has the electromotive force being a mini battery. In contrast, Morris uses a galvanic power source, and literally teaches away from using mini batteries as being expensive and not self-contained or portable. (*See, e.g.*, Morris, column 1, lines 56-60 and column 2, lines 11-14). In view of the lack of a mini battery, Morris has no need for the claimed “shunt resistance disposed in parallel with an ion conducting path between said cationic and anionic chambers, said shunt resistance selected to control the delivery of drug from the iontophoretic fluid delivery device dependent on the mini battery’s capacity”. For these two reasons, Morris is not believed to anticipate claim 32.

Claims 33 and 36 have been canceled herein, thus obviating the need to respond to that portion of the rejection. With respect to dependent claims 34 and 35, they depend from unanticipated claim 32 and should distinguish from Morris for at least the same reasons.

Claims 32-36 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 4,292,968 to Ellis. Applicant respectfully traverses the rejection.

Ellis does not disclose an electromotive force consisting of a mini battery together with a shunt resistor configured with anionic and cationic chambers as in amended claim 32. Accordingly, Ellis cannot anticipate claim 32 and the claims dependent thereon.

Claims 1, 6, and 10 are rejected as being obvious over Morris in view of Phipps. Applicant respectfully traverses the rejection.

First, without applicant’s disclosure, there would have been no motivation to combine the two references. Morris teaches against using a mini battery as a first electromotive cell as

claimed in claim 1. (*See, e.g.*, Morris, column 1, lines 56-60 and column 2, lines 11-14). In view of the lack of a mini battery, Morris cannot suggest the claimed “shunt resistance disposed in parallel with an ion conducting path between said cationic and anionic chambers, said shunt resistance selected to control the delivery of fluid from the iontophoretic fluid delivery device” in order to drain the mini battery and deliver the correct dose of fluid to the body.

As specifically noted in paragraph [0060] of the application, “The current discharge through both the shunt and skin paths exceeds the battery's steady state discharge rate at which battery voltage may remain relatively constant. However, the voltage does exhibit a sharp drop as the battery approaches full discharge. The battery inherently expends its energy more rapidly and uniformly than the electrolytic cell, and does so up to substantially complete exhaustion. Such a characteristic is desirable as one way accurately to control a treatment dose. The device according to the invention provides a disposable iontophoretic [apparatus] which is faster in delivering a treatment dose and also more precise in termination of the treatment interval.”

Second as can be determined by the foregoing, even combining the references, one would still not arrive at the invention claimed in claims 1, 6, and 10 of the application. Neither reference discloses the desirability of using a single approximately square-wave current discharge to deliver a drug in an iontophoretic fluid delivery device, and neither reference teaches or suggests the claimed device.

Accordingly, applicant requests that the rejection be withdrawn.

Conclusion

The application should be in condition for allowance. If questions should remain, however, after consideration of the foregoing, the Office is kindly requested to contact applicant's attorney at the address or telephone number given herein.

Respectfully submitted,



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